

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS : Bunn, et al.  
SERIAL NUMBER : 10/772,076 EXAMINER : Yong D. Pak  
FILING DATE : February 3, 2004 ART UNIT : 1652  
FOR : COMPOSITIONS AND METHODS OF TREATING DIABETES

**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

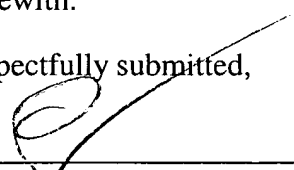
Transmitted herewith for filing in the above-referenced patent application are the following documents:

1. Supplemental Information Disclosure Statement (2 pages), in duplicate;
2. Modified Form 1449/PTO (2 pages), in duplicate;
3. Copies of cited references B3; C4-21; and
4. Return postcard.

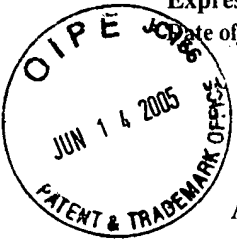
If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at 617-542-6000, Boston, Massachusetts.

The Commissioner is authorized to charge any fees that may be due, or to credit any overpayment, to the undersigned's account, Deposit Account No. 50-0311 Ref. No. 18989-032. A duplicate copy of this transmittal letter is enclosed herewith.

Respectfully submitted,

  
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Cynthia A. Kozakiewicz, Reg. No. 42,764  
Attorneys for Applicants  
c/o MINTZ, LEVIN  
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Date: June 13, 2005



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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed on the attached modified Form PTO-1449, as well as copies of the listed documents.

This Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action based on the merits in the above-identified case. Accordingly, no fee or certification is believed due. By the waiver of 37 CFR 1.98(a)(2)(i) copies of the U.S. Patents A1-A3 are not submitted.

It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims, and sign the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

By submitting this Supplemental Information Disclosure Statement, the Applicants make no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

APPLICANTS: **Bunn et al.**  
U.S.S.N.: **10/772,076**

Notwithstanding any statements by the Applicants, the Examiner is urged to form his/her own conclusion regarding the relevance of the cited information. An early and favorable action is hereby requested.

Please charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 19898-032.

Respectfully submitted,



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Cynthia A. Kozakiewicz, Reg. No.42,764  
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c/o MINTZ, LEVIN  
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Date: June 13, 2005

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|   |                     |  |   |  |                               |                      |   |
|---|---------------------|--|---|--|-------------------------------|----------------------|---|
| Modified Form 1449/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |                     |  |   | <b>Application Number</b>                  |                               | 10/772,076           |   |
|   |                     |  |   | <b>Filing Date</b>                         |                               | February 3, 2004     |   |
|   |                     |  |   | <b>First Named Inventor</b>                |                               | Bunn                 |   |
|   |                     |  |   | <b>Group Art Unit</b>                      |                               | 1652                 |   |
|   |                     |  |   | <b>Examiner Name</b>                       |                               | Yong D. Pak          |   |
|   |                     |  |   | <b>Attorney Docket Number</b>              |                               | 18989-032            |   |
| <b>U.S. PATENT DOCUMENTS</b>  |                     |  |   |  |                               |                      |   |
| <b>Exam<br/>Initials</b>  | <b>Cite<br/>No.</b> | <b>U.S. Patent<br/>Document No.</b>  | <b>Issue Date</b>   | <b>Name of Patentee(s) or Applicant(s)</b> | <b>Class</b>                  | <b>Sub<br/>Class</b> | <b>Filing Date<br/>If Appropriate</b>     |
|   | *A1                 | 3,625,214  | 12/07/71  | Higuchi                                    | 128                           | 260                  |   |
|   | *A2                 | 4,789,734  | 12/06/88  | Pierschbacher                              | 530                           | 395                  |   |
|   | *A3                 | 4,925,673  | 05/15/90  | Steiner et al.                             | 424                           | 455                  |   |
| <b>U.S. PUBLISHED APPLICATION DOCUMENTS</b>   |                     |  |   |  |                               |                      |   |
| <b>Exam<br/>Initials</b>  | <b>Cite<br/>No.</b> | <b>U.S. Published<br/>Application No.</b>  | <b>Published<br/>Date</b>   | <b>Name of Patentee(s) or Applicant(s)</b> | <b>Class</b>                  | <b>Sub<br/>Class</b> | <b>Filing Date<br/>If<br/>Appropriate</b> |
|   |                     |  |   |  |                               |                      |   |
| <b>FOREIGN PATENT DOCUMENTS</b>   |                     |  |   |  |                               |                      |   |
| <b>Exam<br/>Initials</b>  | <b>Cite<br/>No.</b> | <b>Foreign Patent Document<br/>Office Number</b>   | <b>Name of Patentee(s) or Applicant(s)</b>  | <b>Date of<br/>Publication</b>             | <b>Translation<br/>Yes No</b> |                      |   |
|   | B3                  | WO 89/07136  | WHITEHEAD INSTITUTE FOR<br>BIOCHEMICAL RESEARCH;<br>HOWARD HUCHES MEDICAL INSTITUTE | 08/10/89                                   |                               |                      |   |
| <b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>  |                     |  |   |  |                               |                      |   |
| <b>Exam<br/>Initials</b>  | <b>Cite<br/>No.</b> | <b>Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.</b>  |   |  |                               |                      |   |
|   | C4                  | GENBANK Accession No. AF169803 (2000)  |   |  |                               |                      |   |
|   | C5                  | GENBANK Accession No. AAF04812 (2000)  |   |  |                               |                      |   |
|   | C6                  | GENBANK Accession No. XM229210   |   |  |                               |                      |   |
|   | C7                  | GENBANK Accession No. XP229210   |   |  |                               |                      |   |
|   | C8                  | GENBANK Accession No. P56395 (2004)  |   |  |                               |                      |   |
|   | C9                  | GENBANK Accession No. P00173 (2004)  |   |  |                               |                      |   |
|   | C10                 | GENBANK Accession No. P20070 (2005)  |   |  |                               |                      |   |
|   | C11                 | GENBANK Accession No. AL034347 (2005)  |   |  |                               |                      |   |
|   | C12                 | Gregoriadis <i>Drug Carriers Biol. Med.</i> , pp. 287-341 (Academic Press) (1979)  |   |  |                               |                      |   |
|   | C13                 | Johnson et al. <i>J. Biol. Chem.</i> , 273(52):35147-35152 (1998)  |   |  |                               |                      |   |
|   | C14                 | Kotani et al. <i>Anal. Biochem.</i> , 284(1):65-69 (2000)  |   |  |                               |                      |   |
|   | C15                 | Kotin et al. <i>Proc. Natl. Acad. Sci. USA</i> , 87:2211-2215 (1990)   |   |  |                               |                      |   |
|   | C16                 | Leiter et al. <i>Am. J. Pathol.</i> , 128(2):380-383 (1987)  |   |  |                               |                      |   |
|   | C17                 | Lu et al. <i>Abstracts of the Meeting on Gene Therapy</i> , Sept. 22-26, 1992, Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, <b>Abstract</b> , page 66. |   |  |                               |                      |   |

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Date of Deposit: June 13, 2005

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Attorney Docket No.: 18989-032

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|--|-----|---|
|  | C18 | Morsy et al. <i>J. Cell. Biochem.</i> , Suppl. 17E, pp. 226, <b>Abstract SZ109</b> (1993) |
|  | C19 | Rosenberg et al. <i>N. Engl. J. Med.</i> , 323(9):570-578 (1990)                          |
|  | C20 | Waddington et al. <i>Anal. Biochem.</i> , 292(2):234-244 (2001)                           |
|  | C21 | Zhu et al. <i>Proc. Natl. Acad. Sci. USA</i> , 96(26):14742-14747 (1999)                  |

**\* By the waiver of 37 CFR 1.98(a)(2)(i) copies of the U.S. Patents A1-A3 are not submitted.**

|                       |  |                    |  |
|-----------------------|--|--------------------|--|
| Examiner<br>Signature |  | Date<br>Considered |  |
|-----------------------|--|--------------------|--|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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